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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N-0104]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Consumer Handling of Ready-to-Eat Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by [insert date 30 days after date of publication in the Federal Register].

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Consumer Handling of Ready-to-Eat Foods

Section 402 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 342) authorizes FDA to regulate foods so that they are not adulterated. FDA's research in food safety seeks to reduce the incidence of foodborne illness by improving the ability to find new ways to detect, enumerate, and control pathogens in the food supply. FDA's Center for Food Safety and Applied Nutrition awarded two grants of research funds in September 2001 to support research into consumer refrigeration practices and shelf life for ready-to-eat (RTE) foods entitled "Consumer Storage Length Practices for Ready-to-Eat Foods" and "Consumer Handling of Ready-to-Eat Foods After Purchase."

The information that will be collected concerns consumer handling of RTE food products. The research will provide data on the storage of RTE foods in unopened and opened packages in home refrigerators; consumer understanding of expiration dates; and consumer use of this information in making decisions regarding purchases, consumption, and home storage conditions. The data from these surveys will be used to refine the Department of Health and Human Services and U.S. Department of Agriculture *Listeria monocytogenes* (LM) risk assessment, issued in draft for public comment on January 19, 2001 (66 FR 5515). The values used for home storage of foods in the draft LM risk assessment were largely based on expert opinion, not statistically supportable data. Thus, the consumer storage data from these two grants will improve FDA's confidence in the predicted risks by reducing the uncertainty in consumer practices.

For the "Consumer Storage Length Practices for Ready-to-Eat Foods," approximately 2,400 respondents will be selected from an already existing

nationally representative Web-enabled panel. For "Consumer Handling of Ready-to-Eat Foods After Purchase," a more traditional survey approach will be used and will be conducted in three parts. In part 1, approximately 400 in-person interviews will be conducted in Tennessee, Illinois, Kansas, Missouri, Florida, and New York. Participants will be selected to represent both sexes, different income groups, and education levels, and a wide range of adults from different ethnic groups. In part 2, 100 respondents from part 1 will complete food diaries of specific foods from the day the food dairy is initiated until those foods are consumed or discarded. In part 3, two mass mailings of questionnaires will be conducted one in fall-winter and the second in spring-summer for a total of 2,000 respondents.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN'

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Web-enabled panel survey Interview survey Food diary Mail survey Total	2,400 400 100 2,000	1 . 1 . 2 4	2,400 400 100 2,000	0.25 0.5 0.5 0.3	600 200 50 600 1,450

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

The number of respondents given in table 1 of this document is based on the study design in the two grant applications. The hours per response was

estimated based on experience of the grantees for similar surveys and also on the number of questions to be included in each survey instrument.

Dated:

8-2-00

August 2, 2002.

Margares M. Dotzel,

Associate Commissioner for Policy.

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